PATENT COOPERATION TREA

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*) 21 JAN 2005	
Applicant's or agent's file reference 021182-000410PC	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US04/11982	16 April 2004 (16.04.2004)	16 April 2003 (16.04.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): G01N 33/53 and US Cl.: 435/7.2, 7.21, 7.25, 7.92; 436/501, 509, 516, 519, 172; 422/68.1

Applicant

UNIVERSITY OF PITTSBURGH OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Form PCT/ISA/237 (cover sheet) (January 2004)

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2, 6-8, 13, 14, and 15-25	YES
	Claims	1, 3-5, and 9-12	NO
Inventive step (IS)	Claims	2, 6-8, 13, and 14	YES
	Claims	1, 3-5, 9-12, and 15-25	NO
Industrial applicability (IA)	Claims	1-25	YES
	Claims	NONE	NO

2. Citations and explanations:

Please See Continuation Sheet

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Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claim 1, 3-5, 9, and 10 lack novelty under PCT Article 33(2) as being anticipated by Manzi S et al. (Sensitivity and specificity of plasma and urine complement split products as indicators of lupus disease activity. Arthritis and rheumatism, (July, 1996), vol. 39, no. 7, pages 1178-88 (Abstract).

Manzi et al. teach that C4d complement associated with platelets has been related and used as a sensitive diagnostic marker in monitoring and predicting degrees of systemic lupus erythematosus (SLE) activity. Manzi detects the C4d complement using quantitative immunoassay methods, i.e. Western blot.

Claim 1 lacks an inventive step under PCT Article 33(3) as being obvious over Manzi S. et al. (New insights into complement: a mediator of injury and marker of disease activity in systemic lupus erythematosus. Lupus, (2004), vol. 13, no. 5, pages 298-303 (Abstract)).

Manzi et al. teach that C4d has been related and used as a screening marker in monitoring and diagnosis of systemic lupus erythematosus (SLE).

Manzi et al. differs from the instant invention in failing to teach that the C4d complement is associated to platelets.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to measure for the level of C4d associated with platelet cells, since platelets are an obvious variation of blood cells having the similar association to the C4d complement.

Claims 11, 12, and 15-25 lack an inventive step under PCT Article 33(3) as being obvious over Manzi S et al. (Sensitivity and specificity of plasma and urine complement split products as indicators of lupus disease activity. Arthritis and rheumatism, (July, 1996), vol. 39, no. 7, pages 1178-88 (Abstract).

Manzi et al. differs from the instant invention in failing to teach a kit format. Manzi et al. also do not teach a software program that commands and automates performance of the assay and diagnosis method.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have incorporated the antibodies and reagents used in the assay method of Manzi into a kit format because kits are conventional .... Additionally, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the method steps into a computer software program because automation of known assay methods is conventional and well within ordinary skill.

Claims 2, 6-8, and 13-14 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest using CD42b associated with platelets as a diagnostic marker for screening and monitoring SLE.

Claims 1-25 meet the criteria set out in PCT Article 33(4), and thus has industrial applicability in the field of diagnostic medicine because the subject matter claimed can be made or used in industry.

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Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

Yasuda M. et al. (Serum C4 levels in patients with SLE in remission. Modern Rheumatology, (2002). Vol. 12, no. 3, pages 213-218) teach general state of the art.